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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,553	11/28/2000	Peter S. Lu	020054001130	7232

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EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/724,553	Lu et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 10, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-17* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-17* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Detailed Action

1. A restriction is required under 35 USC 121 between one of the following groups:

Groups 1-578, Claims 1-8 and 16-17, drawn to a method of modulating a biological function of a cell comprising introducing into the cell an agent or antagonist that inhibits the binding of a PDZ protein and a PL protein in the cell, wherein said PDZ protein is one of the 34 PDZ proteins recited in claims 3 and 4, and wherein said PL protein is one of the 17 PL proteins recited in claim 2, classified in class 514, subclass 12,

Groups 579-1190, Claim 9, drawn to a method of determining whether a test compound is an inhibitor of binding between a PDZ protein and a PL protein, wherein said PDZ protein is one of the 34 PDZ proteins recited in claims 3 and 4, and wherein said PL protein is one of the 18 PL proteins recited in part ii of the instant claim, classified in class 435, subclass 7.1,

Groups 1191-1208, Claims 10-12, drawn to an inhibitor of binding a PDZ protein and a PL protein, wherein said inhibitor is a peptide comprising a sequence that is from about 3 to about 20 residues of a C-terminal sequence of one of the 18 PL proteins recited in part (a) of claim 11, or pharmaceutical composition thereof, classified in class 530, subclasses 326-330,

Groups 1209-1226, Claims 10-12, drawn to an inhibitor of binding a PDZ protein and a PL protein, wherein said inhibitor is a peptide mimetic of a peptide comprising a sequence that is from about 3 to about 20 residues of a C-terminal sequence of one of the 18 PL proteins recited in part (a) of claim 11, respectively, or pharmaceutical composition thereof, classified in class 530, subclass 300,

Groups 1227-1244, Claims 10-12, drawn to an inhibitor of binding a PDZ protein and a PL protein, wherein said inhibitor is a small molecule, or pharmaceutical composition thereof, and wherein the PL protein is one of the 18 PL proteins recited in part (a) of claim 11 classified in class 514, subclass 1,

Groups 1245-1262 Claims 13-15, drawn to a method for treating a disease, comprising administering an inhibitor of Groups 1191-1208, respectively, classified in class 424, subclass 184,

Groups 1263-1280, Claims 13-15, drawn to a method for treating a disease, comprising administering an inhibitor of Groups 1209-1226, respectively, classified in class 424, subclass 184,

Groups 1281-1298, Claims 13-15, drawn to a method for treating a disease, comprising administering an inhibitor of Groups 1245-1244, classified in class 424,

subclass 184,

Note: Each claim will be examined only to the extent of the elected invention.

The inventions are distinct, each from the other because:

2. Groups 1-578 / 579-1190 / 1245-1298, are unique methods because of their differing and distinct endpoints consisting of a method of modulating a biological function, a method of determining whether a test compound is an inhibitor of binding between a PDZ protein and a PL protein, and a method of treating a disease. Though Groups 1245-1298 have identical endpoints, they differ with respect to the ingredients administered. Therefore, Groups 1-578 / 579-1190 / 1245-1298 are patentably distinct, each from the other.

3. Groups 1191-1244 are unique products. The inhibitors differ with respect to their structure and biochemical /physicochemical properties, and are therefore patentably distinct.

4. Groups 1191-1208 and Groups 1245-1262, respectively, are related as product and process of use, as are Groups 1209-1226 and Groups 1263-1280, respectively, as are groups 1227-1244 and Groups 1281-1298, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the inhibitor, can be used as an immunogen in a method of producing monoclonal antibodies, as well as in a method for treating a disease.

5. Groups 1191-1244 and Groups 1-578 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the inhibitor, can be used as an immunogen in a method of producing monoclonal antibodies, as well as in a method of modulating a biological function of a cell.

6. Groups 579-1190 and Groups 1191-1244 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and

materially different process (MPEP § 806.05(f)). In the instant case, the product, the inhibitors, can be made using synthetic methods of chemical synthesis and/or recombinant molecular genetics, as well as in a method of screening.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

8. A) If one of Groups I-578 is elected, the applicant is further required under 35 U.S.C. 121:

to elect a method comprising a **specific cell type**, such as an endothelial cell or hematopoietic cell as recited in claim 1,

to elect a method of modulating a **specific biological function**, such as one of the functions disclosed on page 29, lines 5-12 of the instant specification,

to elect a **specific carboxy-terminal amino acid motif of a PL protein**, wherein said motif correlates with its respective motif as disclosed on pages 9-10 of the instant specification,

B) If one of Groups 1245-1298 is elected, the applicant is further required

to elect a method comprising a disease characterized by **a specific type of response**, such as an inflammatory response, a humoral response or an autoimmune disease as recited in claims 14-15.

9. Claims 1-8 and 13-17 are generic, for example.

10. The species are distinct each from the other for the following reasons:

A) Specific biological functions and specific types of responses, each encompass different cell types and proteins.

B) Specific cell types differ with respect to their biological function and biophysical characteristics,

C) amino acid sequences differ with respect to their biochemical structure and function,

11. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers **(other than elections)** should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
March 20, 2002
Amy DeCloux 3-20-02